

REMARKS

Claims 1-51 are pending. Of these, claims 41 and 42 were withdrawn from consideration as being duplicates of claims 39 and 40, respectively. Claims 1, 19, 43, 44 and 51 have been amended. New claim 52 has been added.

Applicant respectfully submits that the present amendments are fully supported by the specification. Specifically, the claimed "bent or deformed porous body maintaining its radius curve", i.e., its bent or deformed shape, is supported at page 11, lines 18-20, for instance. The claimed device not requiring ingrowth of tissue into it is supported, for example, in the paragraph bridging pages 12 and 13.

The present invention is directed to a medical device that fixes in place one or more tissues (such as bone) of a living body. The device, although porous, is sufficiently rigid as to prevent the fixed tissues from shifting during the healing process. It is desirable to be able to contour or shape the device to some desired conformation, and to be able to hold or maintain that new shape. Accordingly, at least a portion of the pores are designed to at least partially but irreversibly collapse during the shaping process. In doing so, the device will not crack or fail catastrophically, but instead can be smoothly bent, as a radius curve will form at the bend. Among the advantages of the claimed "pore collapsing technique" is the ability to deform the device to the desired shape at room temperature. Many prior art devices require heating above the polymer's glass transition temperature to be able to permanently deform the polymer material to some desired shape.

Claim Objections

Claims 41 and 42 were objected to under 37 CFR §1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, the Action stated that claims 41 and 42 are duplicates of claims 39 and 40, respectively. Applicant respectfully traverses this position. Applicant respectfully submits that claim 39 recites that the third layer has the first pore density, but claim 41 recites that the third layer has a third pore density. Claim 42 is different from claim 40 for this same reason. Accordingly, this objection should be withdrawn, and claims 41 and 42 should be examined, Applicant respectfully submits.

Claim Rejections – 35 USC §102

Claims 1-13, 15-31 and 33-51 were rejected under 35 U.S.C. §102(b) as being anticipated by European Patent Publication No. EP 0 562 864 A1 to Rosenthal (hereinafter referred to as "Rosenthal"). Applicant respectfully traverses this rejection.

Applicant respectfully submits that Rosenthal neither discloses nor suggests the claimed invention. Rosenthal discloses a wound dressing and/or implant material comprising a matrix structure of sponge, and at least one substructure. The matrix is preferably strong and **resilient enough to resist collapse** and may be cut and/or formed so as to conform to a wound shape so that it protects and/or fills a wound bed. See column 4, lines 26-29. The Action states that the

Rosenthal sponge is compressible by virtue of its collapsing pores. Applicant's response is that, to the extent the Rosenthal pores collapse, the collapse must be reversible and the sponge must revert to its original shape upon removal of the deforming force. Otherwise, the above-quoted statement by Rosenthal cannot be reconciled. Thus, Rosenthal teaches away from the claimed polymer tissue fixation device, at least a portion of whose pores at least partially collapse during deformation of the device to form a radius curve, and wherein the claimed device retains its deformed shape, even after the deforming force is released or removed. Moreover on this last point, Rosenthal neither discloses nor suggests the property of maintaining the new shape after bending or other deformation.

Accordingly, this rejection should be withdrawn, Applicant respectfully submits.

Claim Rejections – 35 USC §103

Claims 14 and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rosenthal in view of U.S. Patent No. 6,306,424 to Vyakarnum (hereinafter referred to as "Vyakarnum"). Applicant respectfully traverses this rejection.

Applicant respectfully submits that neither Rosenthal nor Vyakarnum, whether taken individually or in permissible combination, discloses or suggests the claimed invention. Rosenthal teaches an implant resilient enough to resist collapse. Vyakarnum seems silent on the issue of collapsible pores. However, if he does not disclose or suggest such collapsing pores, then he fails to remedy this deficiency in Rosenthal. On the other hand, if Vyakarnum were to disclose irreversibly collapsible pores, it would then be at odds with Rosenthal and therefore uncombinable, Applicant respectfully submits.

Applicant furthermore respectfully submits that Vyakarnum neither discloses nor suggests the claimed ability to hold the new shape following deformation.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Applicant appreciates the examiner's acknowledgement of Applicant's Information Disclosure Statement on 06/11/2006.

Conclusions


The claimed device possesses the property of maintaining its new shape upon deformation. This is valuable because the surgeon typically has to shape the fixation device to the precise contours required by each patient's surgery. It is also valuable to have a fixation device that is sufficiently rigid to prevent the fixed tissue(s) from shifting, but also able to avoid its cracking or breaking during the shaping (deformation) process.

In view of the amendments and the remarks herein, Applicant respectfully submits that the instant application is in condition for allowance. Accordingly, Applicant respectfully requests issuance of a Notice of Allowance directed to claims 1-52.

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Should the Examiner deem that any further action on the part of Applicant would be desirable, the Examiner is invited to telephone Applicant's undersigned representative.

Respectfully submitted,


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